

## Assessment of Quality Of Life with Different Radiotherapy Schedule in Palliative Management of Advanced Carcinoma Esophagus

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**Abstract:** Esophageal cancer is an aggressive malignancy usually associated with a poor prognosis due to loco- regional failure and distal metastasis. The major goal of therapy is restoring and/or maintaining the ability to swallow with minimum morbidity and with reasonable QOL. A prospective Interventional study done at S.G.P.T. Cancer Hospital, M.G.M Medical College Indore with previously untreated, inoperable locally advanced carcinoma of esophagus with palliative intent. A total sixty patient were taken in this study from September 2011 to Sept 2012 and randomly allocate to three ARM Interventional study of three different radiation regimens. The QOL was assessed using the European Organization for Research. We have taken QOL of the patients as an important factor for optimization of treatment schedule to be used for palliation and analyzed the same using QLQ c-30 and QLQ OES -18 questionnaires. Improvement in mean dysphasia grade at 15 days, 1 month and 3 month was nearly equal for all the three arms with maximum improvements in Arm A. The increase in mean global health status score were comparable in Arm A, B, C at one month and three months. The mean physical functioning score also improved in the entire three radiation regimen at one month and three months. While the symptom score decreased after treatment in all the three arms indicating the comparable improvement in symptoms and related complaints after the radiation therapy. Thus any of the three radiation schedules used in Arm A, Arm B and Arm C achieve good palliation with minimal morbidity.

**Keywords:** Carcinoma of esophagus, Colour Doppler, Dysphasia, Esophagitis, External radiotherapy Co-60, Mean global health status score, Quality of life

## INTRODUCTION

Esophageal cancer is an aggressive malignancy usually associated with a poor prognosis due to loco regional failure and distal metastasis [1]. Unfortunately, about 60-70% of the patients are undernourished and in advanced stages of disease at presentation [2]. In a majority of these patients, quality of life (QOL) takes precedes over long-term prognosis. The major goal of therapy is restoring and/or maintaining the ability to swallow with minimum morbidity and with reasonable QOL. A prospective Interventional study done at S.G.P.T. Cancer Hospital, M.G.M Medical College Indore with previously untreated, inoperable locally advanced carcinoma of esophagus with palliative intent. A total sixty patient were taken in this study from September 2011 to sept 2012 and randomly allocate to three ARM Interventional studies of three different radiation regimens. The QOL was assessed using the

European Organization for Research and also compare the three different radiation schedules for radiation toxicity (if any), in carcinoma esophagus. We have taken QOL of the patients as an important factor for optimization of treatment schedule to be used for palliation and analysed the same using QLQ c-30 and QLQ OES -18 questionnaires. Improvement in mean dysphasia grade at 15 days, 1 month and 3 month was nearly equal for all the three arms with maximum improvements in Arm A. The increase in mean global health status score were comparable in Arm A, B, C at one month and three months. The mean physical functioning score also improved in the entire three radiation regimen at one month and three month. While the symptom score decreased after treatment in all the three arms indicating the comparable improvement in symptoms and related complaints after the radiation therapy. Thus any of the three radiation schedules used

in arm A, arm B and arm C achieve good palliation with minimal morbidity.

**MATERIAL AND METHODS**

**Study design**

A prospective Interventional study done at S.G.P.T. Cancer Hospital, M.G.M Medical College Indore with previously untreated, inoperable locally advanced carcinoma of esophagus with palliative intent referred to Cancer Hospital from the Department of Surgery and Medicine, M.G.M. Medical College, Indore or approach directly to our department from outside and had disease at that time.

A total sixty patient were taken in this study from September 2011 to September 2012. Informed consent were be taken before enrolling the patient into the study.

**PRETREATMENT EVALUATION**

Detailed history, Complete physical examination, Detailed description of primary growth and regional lymph node, Upper GI Endoscopy and biopsy, Staging by Fibre- optic esophagoscopy, C.T chest e.t.c, routine investigations - Blood Investigation & Radiographic Evaluation:

**Eligibility Criteria**

**Minimal requirement for eligibility to participate in this study –**

- Karnofsky performance status: > 50,
- Hb > 8g/dl
- Total leukocyte count (TLC) > 4000/mm<sup>3</sup>
- Platelet count (PC) > 100,000/mm<sup>3</sup>,

**INCLUSION CRITERIA**

- All the subjects in the study are histopathologically proven cases.
- All the patients are made aware of the purpose and the design of the study and only after their consent they are included in the study.
- The patients included in the study had not received any prior radiotherapy or chemotherapy for the disease.
- September Biopsy-proven squamous cell carcinoma.
- Tumor more than or equal to 5 cm in length on endoscopy and/or barium swallow.
- Surgically inoperable disease.
- Age: 17-80 years.
- Karnofsky performance score > 50.

**SKIN REACTION**

**Early reaction**

Grade 0:	Nil
Grade I:	Erythema
Grade II:	Early desquamation/Pigmentation
Grade III:	Moderate dry desquamation/ Early moist desquamation
Grade IV:	Blister/Skin pigmentation/Bleeding ulcer

- No prior malignancy in the past 5 years.

**Exclusion criteria**

- Patient not willing to give consent.
- Patient with history of prior Chemotherapy or Radiotherapy

**TREATMENT PROTOCOL**

The patients were planned and following barium swallow examination, fields will marked and checked on plain radiographs. The fields used were a pair of parallel-opposed AP-PA fields so as to cover the tumor adequately along with a safety margin of 5 cm proximally and distally & 2-3 cm laterally. External radiation will delivered with megavoltage photon beams of Co-60.

Patients with inoperable, carcinoma of the esophagus were randomly allocated to Arm-A (external radiotherapy 30 Gy/10 fractions/2 week, Arm-B (external radiotherapy 20 Gy /5 fractions/1 week) and Arm-C (external radiotherapy 30.5Gy /5 fractions/once a week). The QOL was assessed using the European Organization for Research and Treatment of Cancer questionnaire at presentation, after treatment and at 3 months follow-up.

During the study, the patient was hospitalized and given symptomatic treatment as and when needed. Patient was reviewed weekly from the start of treatment and as and when required. In addition, was evaluated for toxicities arising from radiation modalities. In case of severe toxicity radiotherapy was stopped till patient got relieved.

**During the therapy, a checklist was used for:**

- Tumour response in terms of symptomatic improvement in dysphagia.
- Radiotherapy related reactions such as skin and mucosal reaction.

**CRITERIA FOR EVALUATING THE RESPONSE**

Complete Response (CR): No evidence of the pretreatment tumor and symptoms and no recurrence within one month. Partial responses (PR): More than 50% of regression of loco-regional disease. No response (NR): Less than 50% regression or no regression at all or progressive disease. Progression – increase in the size of growth during treatment

**Late reaction (> 3 months)**

Grade 0:	Nil
Grade I:	Slight atrophy, pigment change, hair loss
Grade II:	Patchy atrophy or hair loss, moderate telangiectasia,
Grade III:	Marked atrophy, total hair loss, gross telangiectasia
Grade IV:	Ulceration, bone exposed

**Follow up**

The patients were discharged after treatment and are being followed up

- Every one to two months for first 2 years.
- Six monthly for next 3 years.
- Annually thereafter.

During each visit, thorough physical examination was conducted along with CBC, LFTs, RFT, Chest X-Ray, Barium swallow study, USG abdomen and any other investigation when indicated. Any recurrences and their patterns were carefully looked for and appropriate treatment advised

**Health Related Quality Of Life (HRQOL)**

For quality-of-life assessments, the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ)-C30 and the lung cancer-specific module QLQ-OES 18 were used. The core questionnaire incorporates five functional scales (physical, role, emotional, cognitive, and social), three symptom scales (fatigue, nausea or vomiting, and pain), a global health and overall quality-of-life scale, and five single items (dyspnea, appetite loss, sleep disturbance, constipation and diarrhea, and financial impact of the disease and its treatment). The QLQ-OES 18 module contains items for measuring dysphasia, eating problems, reflux problems pain trouble swallowing saliva. Choked when swallowing dry mouth, trouble with taste, trouble with coughing and trouble with talking. All scales and single items were linearly transformed to a scale from 0 to 100, with a higher score on functional scales indicating a high degree of function, and a higher score on the symptom scales indicating a high degree of symptoms. The patients completed the questionnaire before the treatment at 1 month after the treatment and at 3 month. Reassessment of patients were be done by-

- **Symptom relief(Dysphasia, odynophagia)**

**Examination**

- General
- Local examination (change in skin colour, reactions)

**Investigations**

- Routine Investigations(Haemogram, Urea & creatinine)
- X-ray barium swallow
- USG (whole abdomen& Pelvis)

**The response was be described as either**

- Complete Response
- Partial Response
- No Response/ Progression

**RESULT**

Data of total sixty patients were taken in this study.

**Incidence**

During this study which lasted over a year, the total number of cancer patients registered in the Department of Radiotherapy was 2945. Of these 123 patients had carcinoma esophagus. Based on the above data, it was found that esophageal cancer comprised 4.1% of all cancers. In the present study total 65 patients were enrolled for the study, out of which 60 cases remained in the study for the analysis of treatment outcome - 20 in Arm-A , 20 in Arm-B and 20 in Arm C.

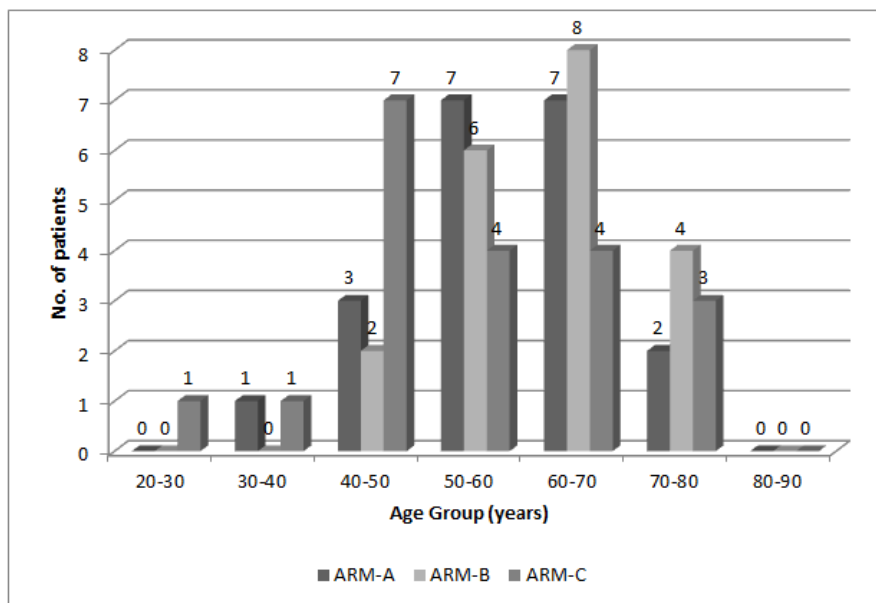
**Age & sex distribution**

Majority of cases in the study were in the age group 60-70 years, accounting for 31.6 % of the total cases. The mean age was 56.6 yrs in Arm-A and 60.6 yrs in Arm-B and 52.8 years in Arm C. Average age being 56.6 years. This study predominantly involves males (34) with a male to female ratio of 1.3:1. Thus in the present study, the disease was found to be more common in men & occurred in advanced age.

**Table-1: Age wise distribution**

Age group (years)	ARM-A	ARM-B	ARM-C	TOTAL	Percentage
20-30	0	0	1	1	1 (1.6% )
30-40	1	0	1	2	2 (3.3%)
40-50	3	2	7	12	12 (20%)
50-60	7	6	4	17	17 (28.3%)
60-70	7	8	4	19	19 (31.6%)
70-80	2	4	3	9	9 (15%)
80-90	0	0	0	0	0 (0%)

The youngest patient in the study was of 27 yrs of age, and the oldest was 79 yrs of age.



**Table-2: Male and female distribution**

No. of patient	MALE	Percentage	FEMALE	Percentage
ARM-A(n=20)	11	55%	9	45%
ARM-B(n=20)	13	65%	7	35%
ARM-C(n=20)	10	50%	10	50%
TOTAL (n=60)	34	56.6%	26	43.4%

The ratio of male: female was 1.3:1

The distribution of cases according to socio-economic status was almost similar in all three groups with majority of the patients belonging to lower socio-economic class.

**Distribution according to socio-economic status**

**Table-3: Hindu and Muslim population distribution**

Treatment ARM	HINDU	Percentage	MUSLIM	Percentage
ARM-A	16	80%	4	20%
ARM-B	17	85%	3	15%
ARM-C	18	90%	2	10%
TOTAL	51	85%	9	15%

The population of hindu is predominant over muslim population in the study. Patients with hindu

religion was 85% and patient with muslim religion was 15%.

**Table-4: Rural and Urban distribution**

Treatment ARM	RURAL	Percentage	URBAN	Percentage
ARM-A	13	65%	7	35%
ARM- B	12	60%	8	40%
ARM-C	16	80%	4	20%
TOTAL	41	68.3%	19	31.7%

The rural population was 68.3% of the total patients and the patient belongs to urban region was 31.7% of the total number of patients

**SYMPTOMATOLOGY**

Dysphagia was the most common complaint at presentation in esophageal cancer patients in present

study and was present in almost all (96%) patients especially for solids. Next most common presenting complaint was weight loss in both the groups

accounting for 87% cases. Odynophagia, dry cough and hoarseness were the next common presentations in 23.4%, 21.3% and 6.4% respectively.

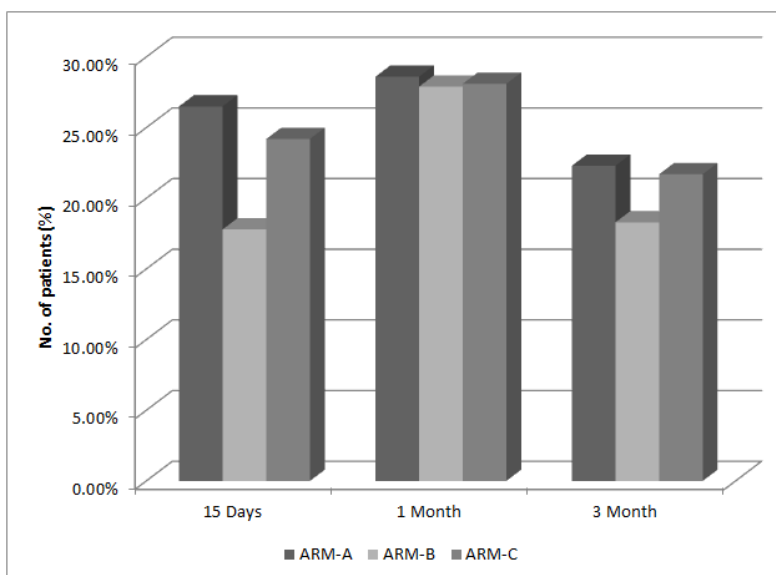
**Table-5: Symptoms wise distribution**

Symptoms	No. of patients	Percentage
Dysphagia	58	96.6%
Weight loss	52	86.6%
Odynophagia	14	23.3%
Dry cough	13	21.6%
Hoarseness	4	6.6%

**Table -6: Improvement in mean dysphasia grade**

Treatment arms	15 Days	1 Month	3 Month
ARM-A	26.5%	28.6%	22.3%
ARM-B	17.8%	27.9%	18.3%
ARM-C	24.2%	28.1%	21.7%
TOTAL	22.8%	28.2%	20.7%

The improvement in mean dysphasia grade is nearly equal in all the three arms at interval of 15 days, 1 month and 3 months.



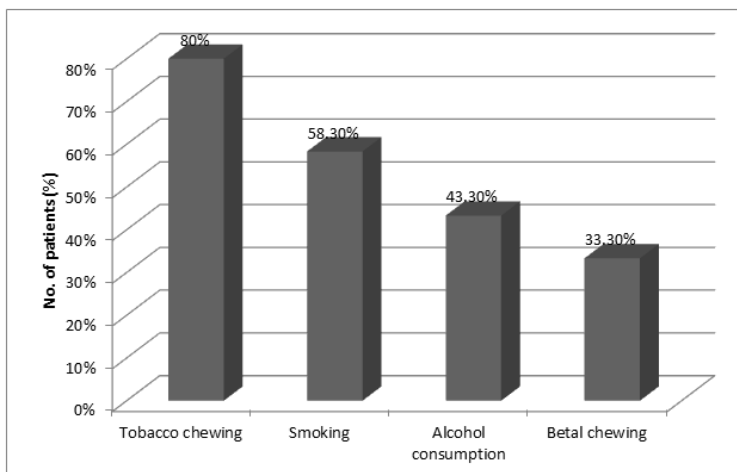
**Association with addiction and dietary habits**

Tobacco chewing and smoking came out to be the most frequent forms of addiction with prevalence in the study of 80% and 58.3% respectively. Esophageal cancer in this study predominantly involves males, that

can be attributed to the use of tobacco and tobacco related products. In the present study, esophageal cancer was found to be more common in Non-vegetarians as against vegetarians (78.7% Vs. 21.3%), though this association was not statistically significant.

**Table -7: Addiction profile**

Addiction type	No of patient	Percentage
Tobacco chewing	48	80%
Smoking	35	58.3%
Alcohol consumption	26	43.3%
Betal chewing	20	33.3%



**Lymph nodal status**

As noted on CT scan Chest/ Abdomen, only 29.8% of patients were found to have gross loco -

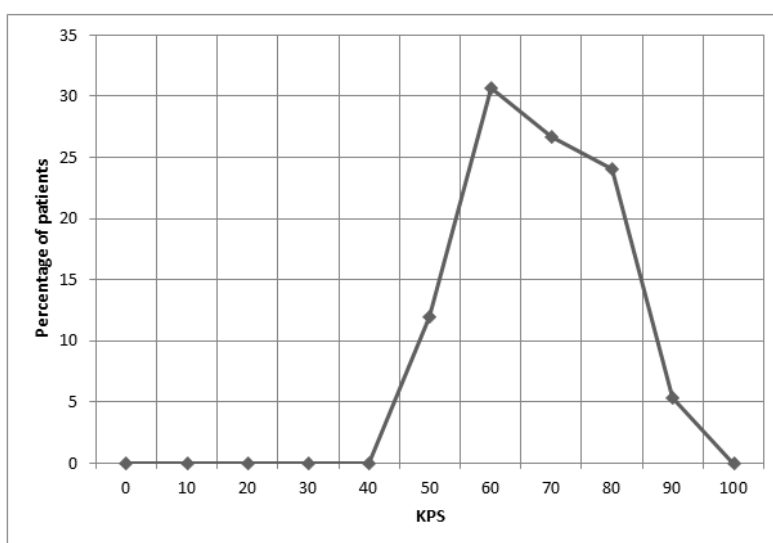
regional lymph nodal involvement, though almost all patients had some local soft tissue extension.

**Performance status**

**Table - 8: Karnofsky Performance Status**

PERFORMANCE SCORE	NO. OF PATIENTS	PERCENTAGE
0	0	0
10	0	0
20	0	0
30	0	0
40	0	0
50	7	12
60	19	30.66
70	17	26.66
80	14	24
90	3	5.33
100	0	0

Studied patients had 50 to 90 performance scores majority of patients had presented with poor KPS (50-60)





**RESPONSE ASSESSMENT**

A total of 60 patients of locally advanced carcinoma of the esophagus were included in the study. The patient characteristics are shown in Table 9. No significant differences were found between Arms A, B and C with respect to age, sex, histology, location

disease and baseline blood results [Table 9]. The most common location was the middle 1/3 (53.3%) and the most common histology (45%) was squamous cell carcinoma. The endoscope was not negotiable in 78.3% of the patients at the time of presentation.

**Table-9: Patient and tumour characteristics**

VARIABLES		ARM- A	ARM-B	ARM-C
		(n=20)	(n=20)	(n=20)
Age	(in years, mean)	56.6	60.6	52.85
Sex	Male (n=34)	11	13	10
	Female (n=26)	9	7	10
Location	Upper 1/3 (n=10)	3	4	3
	Middle 1/3 (n=32)	9	12	11
	Lower 1/3 (n=18)	9	5	4
Biopsy (squamous cell carcinoma)	Keratinizing (n=18)	4	7	7
	Nonkeratinizing (n=15)	4	4	7
	Not otherwise specified(n=27)	13	10	4
Endoscopy	Negotiable (n=13)	4	4	5
	Not Negotiable(n=47)	17	17	12

After the initial follow up of 1 month, assessment of response to therapy was made. Compliance to the therapy was high.

**QOL scores**

QOL assessment was performed using the validated questionnaire developed by the EORTC. The questionnaire modules used were EORTC QLQ-C30 and EORTC QLQ-OES 18. Permission was obtained from the EORTC for using their questionnaire for this study [3, 4].

**GENERAL SCORE (QLQ C30)****Global health status**

The mean global health status score was 30 before treatment in arm A, which improve to 44 after completion of treatment, further improving to 55 at the 3 months interval. In Arm B it was 24 before treatment, become 40 after completion of treatment and 37 at 3 months. In Arm C it improve from 28 to 42 after treatment, and again increase to 50 at 3 months (Table 11).

**Functional Scores**

The mean physical functioning score in Arm A was 59 before treatment, become 57 after treatment and 64 at 3 months interval. In Arm B it was 55 before treatment increase to 57 after treatment and decrease to 30 at 3 months. In Arm C it was 55 before treatment improve to 57 after treatment and increase to 64 at 3 months. The mean emotional functioning score improved from a 55 pre-treatment score to 66 at 3 months in Arm A while, in Arm B it was 47 before treatment and become 61 at the 3 months interval. In Arm C it improved from 55 to 65 respectively. There is not much change in the mean cognitive functional in all

the three arms after treatment and at 3 months intervals. The mean social functioning score improved from 42 before treatment to 46 at 3 months in Arm A. In Arm B is change 29 to 41 at 3 months and Arm C from 40 to 42 respectively.

**Symptom scores**

On symptom scale valuations the mean fatigue score had decreased from 64 pre-treatment to 60 after treatment and 49 at 3 months in Arm A. In Arm B the score were 74, 67 and 65 respectively. In Arm c it decreased from 63 pre-treatment to 50 at 3 months. The mean nausea/vomiting score was decreased from 42 to 24 at 3 months in Arm A, from 44 to 26 in Arm B and 42 to 23 in Arm C respectively. The mean pain score increased from 57 to 58 after treatment in Arm A which further decreased to 45 at 3 months, In Arm B it decreased from 68 to 62 at 3 months after treatment. In Arm C it was 54 before treatment and 55 after treatment and 44 at 3 months. Result of single item scores like dyspnoea, insomnia, appetite loss, constipation and financial difficulties were also improved all the three arms after treatment. None of the patients had diarrhoea in all three arms before treatment. While 4 patients in Arm A, two patients in Arm B and three in Arm C developed diarrhoea at 3 months which was not related to treatment.

**B) Esophageal score (QLQ OES-18)**

The esophageal mean symptom score were analyzed using an OES-18 questionnaire as shown in Table 11. The symptom score showed marked improvement in all the arms after radiotherapy. Maximum improvement in dysphasia score was seen in Arm A 54.4%, Arm B it was 24% and 46.3% in Arm C at 3 months after radiotherapy. (Table 12) Improvement

in eating problem score at 3 months was maximum in Arm A 31.3% while it was 20% in arm B and 29 in Arm C.

Reflux symptoms scores, infect deteriorate with treatment, In Arm A and B and C at the time

course at 3 months. Pain score improvement in Arm A and B was 34% and 16.9% while in Arm C 30% of the patients show improvement. The single item symptom score also showed improvement has shown in the table 13.

**Table-10: Mean Quality of life scores (QLQ-c30)**

	ARM -A			ARM -B			ARM -C		
	Pre	1 FU	3 Month	Pre	1 FU	3 Month	Pre	1 FU	3 Month
Global health status	30	44	55	24	40	37	28	42	50
Physical scale									
Physical functioning	59	57	64	55	57	30	55	57	64
Roll functioning	58	62	65	52	53	43	54	61	64
Emotional functioning	55	63	66	47	63	61	55	62	65
Cognitive functioning	83	83	81	71	73	72	81	84	83
Social functioning	42	42	46	29	28	41	40	41	42
Symptoms scales									
Fatigue	64	60	49	74	67	65	63	60	50
Nausea and vomiting	42	27	24	44	33	26	42	26	23
Pain	57	58	45	68	62	62	54	55	44
Dyspnoea	2	5	2	3	3	11	2	4	2
Insomnia	51	41	35	63	35	49	51	41	36
Appetite loss	59	57	49	65	62	58	57	56	47
Constipation	43	29	18	54	40	44	42	28	18
Diarrhea	0	0	4	0	0	2	0	0	3
Financial difficulties	59	63	51	81	29	56	58	61	50

**Table-11: Mean Quality of life score (QLQ-OES 18)**

	ARM-A			ARM-B			ARM-C		
	Pre	1 FU	3 month	Pre	1 FU	3 month	Pre	1 FU	3 month
Esophageal symptoms scale/items									
Dysphagia	68	51	31	75	58	57	70	50	43
Eating problems	67	58	46	70	63	56	67	59	43
Reflux symptoms	26	25	28	23	23	32	30	24	30
Pain	46	40	32	53	43	44	44	41	35
Trouble swallowing saliva	28	14	6	30	16	16	25	12	10
Choked when swallowing	60	46	39	76	51	49	59	45	44
Dry mouth	14	19	14	6	10	18	14	20	15
Trouble with taste	30	43	31	17	21	27	24	40	30
Trouble with coughing	3	5	4	1	2	16	2	4	5
Trouble with talking	5	5	4	2	2	11	4	3	4

**Table-12: Percentage improvement in Quality of life score (QLQ OES-18)**

	ARM-A	ARM-B	ARM-C
Improvement in dysphasia score			
First follow-up (%)	25.0	22.6	23.6
3 month (%)	54.4	24.0	46.3
Improvement in eating problems			
First follow-up (%)	13.4	10.0	11.2
3 month (%)	31.3	20.0	29.0
Improvement in reflux symptoms			
First follow-up (%)	3.8	0	2.7
3 month (%)	-7.6	-39.1	-15.5
Improvement in pain score			
First follow-up (%)	13.0	18.8	17.3
3 month (%)	34.0	16.9	30.0



**COMPLICATIONS**

Acute radiation morbidity was assessed using RTOG/EORTC criteria. Esophagitis at 1 month seen in 10 patients in arm A, eight patient in arm B, nine patient in arm C. The entire patient had only grade1/grade2 esophagitis. No stricture formation was seen. Dysphasia at follow up was due to progression of disease rather than stenosis. Tracheo-esophageal fistula developed in one patient in arm B at 1 month and one patient in arm A at six months. None of the patient in arm C developed trachea-esophageal fistula.

Additional procedure to restore feeding(in the form of nasogastric tube insertion, endoscopic dilatation/stenting or feeding jejunostomy) were required in 3 patient at three month and 5 patient at six month in Arm A. In Arm B, eight patient at 3 month and six patients at 6 month. In Arm C four patients at 3 month and seven patients at 6 month, needed additional procedure for relief of dysphasia.

**Table-13: Radiation toxicity**

Toxicity scores	ARM A	ARM B	ARM C	TOTAL	
1 month	0	8	7	7	22
	1	9	7	6	22
	2	1	1	1	03
3 month	0	5	7	6	18
	1	6	5	5	16
	2	4	0	1	05
6 month	0	2	2	1	05
	1	3	2	2	07
	2	2	2	0	04

**Table-14: Additional procedure to restore nutrition**

Procedure	Treatment Arms			Total
	Arm A	Arm B	Arm C	
AT 3 month				
RT insertion	2	5	3	10
Endoscopic dilatation	-	1	1	02
Feeding jejunostomy	1	2	-	03
Total	3	8	4	

**Rtog-15: Acute radiation morbidity scoring criteria**

	Grade 0	Grade 1	Grade 2	Grade 3	Grade4
Skin	No change over baseline	Follicular, faint or dull erythema/epilation/dry desquamation/decreased sweating	Tender or bright erythema, patchy moist desquamation/moderate edema	Confluent ,moist desquamation other than skin folds pitting edema	Ulceration, hemorrhage necrosis
Esophagus	No change over baseline	Mild dysphagia or odynophagia/may require topical anaesthesia or non narcotic analgesics/may require soft diet	Moderate dysphagia or odynophagia/ may required narcotic analgesics/may required narcotic analgesics/may require liquiddiet	Severe dysphagia or odynophagia with dehydration or weight loss(>15%) requiring N-G feeding tube,IV fluids or hyperalimentation	Complete obstruction,ulceration, perforation, fistula.

RTOG/EORTC Late Radiation Morbidity Scoring Scheme

Skin	Grade0	No change from baseline
	Grade1	Slight atrophy; pigmentation change, some hair loss
	Grade2	Pathy atrophy, moderate telangiectasia, total hair loss
	Grade3	Marked atrophy, gross telangiectasia
	Grade4	Ulceration
Esophagus	Grade0	No change from baseline
	Grade1	Mild fibrosis; slight difficulty in swallowing solids, no pain on swallowing
	Grade2	Unable to take solid food normally, swallowing semisolid food, dilation may be indicated
	Grade3	Severe fibrosis able to swallow only liquids, may have pain on swallowing, dilation required
	Grade4	Necrosis/perforation/fistula

## DISCUSSION

Esophageal cancer is an aggressive malignancy usually associated with a poor prognosis because of loco regional failure and distal metastasis [1]. Many studies have demonstrated efficacy and safety of external radiotherapy and brachytherapy for palliation of carcinoma of the esophagus [2-4]. In a majority of these patients, quality of life (QOL) takes precedence over long-term prognosis. The major goal of therapy is restoring and/or maintaining the ability to swallow with minimum morbidity and with reasonable QOL.

Blazeby *et al.* [5] in study, defined measurement properties and clinical validity of the EORTC questionnaire module to assess QOL in esophageal cancer. In July 2003, the EORTC issued QLQ OES-18 as the validated questionnaire in which six questions have been eliminated. The analysis was therefore carried out using the QLQ OES-18. The QLQ-OES 18 contains symptom scales like dysphagia, eating trouble, reflux symptoms and pain.

The QLQ-C30 (version 3.0) was used, which is composed of both multi-item scale and single-item measures. Each of the multi-item scales includes a different set of items. No item occurs in more than one scale.

In my experiences, the questionnaire was well accepted and compliance rates were high among patients of carcinoma esophagus. Our study has shown that QOL in terms of global health status, functioning scale and symptom scales improved considerably after different radiotherapy schedules.

Yet in the developing world with financial constraints and very limited resources, only 20 Gy/five fractions regimen could provide an equivalent benefit in symptom relief especially in patients with poor performance status and limited survival thus qualifying to be a cost-effective method of palliation.

Many studies have been done with hypofractionation in squamous cell carcinoma at other sites for palliation. In our experience, with a dose 20Gy /5#/1 week good palliation was noticed, 54% patients

had shown relief of symptom at one month after radiotherapy.

Albertson *et al.* [6] evaluation effect of radiotherapy for esophageal cancer with a dose of 40-45 Gy at a rate of 2 Gy/#. About 45% of patients experienced relief of dysphasia within 2 months of radiotherapy. Although the symptomatic relief is comparable to the present study but it has added advantage of short over all treatment time. By the time acute reactions develop treatment is already over so patient need not stay for longer time in the hospital.

Rathi *et al.* [7] in their study have evaluated swallowing performance after giving 40Gy/4 weeks as palliative EBRT with overall response rate of 80%. In our study with the radiation dose of 30Gy/10#, 56% patients had shown relief of dysphasia at one month after EBRT. So only one study has been reported in literature by Kelsen *et al* [8], where 20Gy/5#/1 wk has been used in carcinoma esophagus in advanced stage with palliative intent they, also reported median survival of 9 months which is comparable to the present study. Only grade 1 & grade 2 radiation morbidity (RTOG grades) was seen in 40.3% of the patients in acute phase (3 months) and 22.6% patients in chronic phase (6 months) in all the arms in toto. The fistulae formation was there in only 2 patients, one each in Arm-B at 3 months and Arm-A at 6 months. the ulceration and stricture formation which require additional procedures (like Ryle's tube insertion / stenting / feeding jejunostomy) were there in 15% of the patients in Arm-A and 40% in Arm-B and 20% of the patients in Arm-C respectively (Tables 15). All of these patients had local disease on endoscopy. Similar results are reported in various series in which palliative doses of radiotherapy were given.

Datta *et al.* [9] reported morbidity in the form of ulcers; strictures and fistulae were observed in 9%, 7% and 5% of patients treated with low dose as compared to 8%, 8% and 13% in those with high dose respectively.

Sharma *et al.*[2] found that 12 Gy in 2 fractions (6Gy per fraction) in advanced carcinoma esophagus gives dysphagia free survival of about 10

months. Overall complication rate was 30% with strictures seen in 15%, ulceration in 10% and fistula in 5%, which is comparable with our study results. The radiation schedules for palliation used in my study were well tolerated with good symptomatic relief and minimum morbidity.

#### SUMMARY AND CONCLUSION

We conducted a prospective THREE ARM Interventional study of three different radiation regimen, 30Gy/10#/2 weeks as arm A, 20Gy/5#/1week as arm B and 30.5 Gy/5#/once a week, under arm C. In this study population of 60 patients were enrolled, most of the patients were of old age group and belongs to rural population. And we concluded as under-

- Most of the patients were of 40-70 age groups (79.9%). The rural population (68.3%) were dominant over urban population (31.7%).
- The male: female ratio was 1.3:1 and 85% population was Hindu & 15% population belongs to Muslim community.
- Dysphagia was most common complaint in patients of all the three arms (96.6%). Improvement in mean dysphagia grade at 15 days, 1 month and 3 month was nearly equal for all the three arms with maximum improvements in Arm A.
- The increase in mean global health status score were comparable in Arm A, B, C at one month and three months.
- The mean physical functioning score also improved in all the three radiation regimen at one month and three month.
- While the symptom score decreased after treatment in all the three arms indicating the comparable improvement in symptoms and related complaints after the radiation therapy.
- Complication due to radiation was of grade I and grade II only, in all the three arms. Esophagitis was most common seen at one month. Only grade I and grade II radiation morbidity (RTOG Grade) was seen in 40.3% of patients in acute phase (3 month) and 22.6% patients in chronic phase(6 month).

Carcinoma of esophagus is an extremely discouraging disease to treat as most patients present in advanced stage and in poor general condition when curative options are limited. So the treatment is done by palliative intent in most cases. Role of radiotherapy is well established for palliation of symptoms in carcinoma esophagus. Thus any of the three radiation schedules used in arm a, arm B and arm C achieve good palliation with minimal morbidity.

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